K060122

510(K) SUMMARY REPORT

MAY 19 2006

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Date Prepared: May 8, 2006

Classification Reference: 21 CFR 872.5570

Device Class: Class II

Product Code: LRK – Anti-Snoring Device

Common /Usual Name: Oral Appliance

Device/Trade Name: Sleep Splint

Predicate Device(s): Snore Guard (K882303)
The Silencer (K954530)

Intended Use:

The Sleep Splint is intended to be prescribed to adult patients to aid in the reduction and management of snoring and mild to moderate obstructive sleep apnea.

Device Description/Technical Characteristics:

The Sleep Splint is a prescription only, intraoral appliance that is fitted to the upper and lower teeth, and worn during sleep for the purpose of reducing the incidence of snoring and obstructive sleep apnea.

The Sleep Splint is made of copolyester (acrylic resin for the previous version) and features an orthodontic resin bond which can be custom-fitted by a dentist. It comfortably holds the mandible 5 mm to 7 mm forward.

An important technical characteristic of this device is its minimal coverage of teeth; only the bite surface is covered by the upper and lower splints. This makes tongue repositioning more comfortable and also enhances fit for patients who have artificial front teeth. Also, by blocking out undercuts of the mold in the process of fabricating the Sleep Splint, it will not only fit the patient more comfortably but also have less impact on each tooth. Clinical/non-clinical data support that these unique characteristics have significantly enhanced patient comfort and ease without sacrificing effectiveness.

Comparisons to Predicate Devices:

The difference between this device and predicate devices is only the design of the device. This difference does not have a significant impact on the safety or effectiveness of the device. All the devices are custom-fitted by a dentist, utilize heat sensitive acrylic or thermoplastic dental/medical grade materials, and comfortably reposition the mandible to keep the airway open.

Published clinical/non-clinical data suggest that the Sleep Splint works in a similar manner to other comparable devices, and the intended use is the same. The general differences between the device and predicate devices are minor and do not raise new safety concerns.

Conclusion:

The Sleep Splint is appropriate for its intended use, and raises no new concerns of safety and effectiveness over the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Nakagawa Dental Clinic
C/O Dr. Maki Sakuraba
Official Correspondent
Makimed, Incorporated
225 First Street
Mineola, New York 11501

MAY 19 2006

Re: K060122
Trade/Device Name: Sleep Splint
Regulation Number: 872.5570
Regulation Name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep apnea
Regulatory Class: II
Product Code: LRK
Dated: May 8, 2006
Received: May 11, 2006

Dear Dr. Sakuraba:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

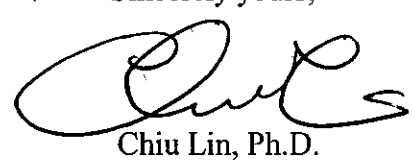
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K060122

Indications for Use

510(k) Number (if known): K060122

Device Name: Sleep Splint

Indications For Use: The Sleep Splint is intended to be prescribed to adult patients to aid in the reduction and management of snoring and mild to moderate obstructive sleep apnea.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...of Anesthesiology, General Hospital,
...ion Control, Dental Devices

...Number: K060122